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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,115	06/24/2003	Ni Ding	10177-191-999	4829
7590 04/15/2010 John J. Gagel, Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804			EXAMINER GANESAN, SUBA	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 04/15/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/603,115

Applicant(s)

DING ET AL.

Examiner

SUBA GANESAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 111-178 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 111-178 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/11/09, 6/19/09.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

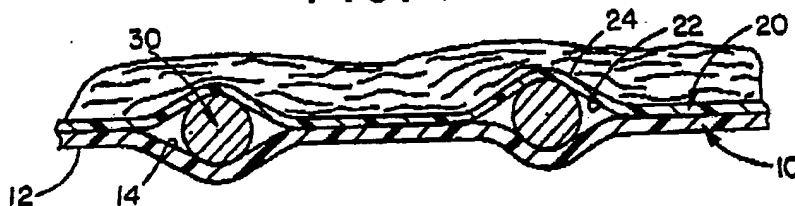
Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/2009 has been entered.

Response to Arguments

2. Applicant's arguments filed 5/4/2009 have been fully considered but they are not persuasive. Applicants have amended the claims to recite that at least a portion of the undercoat covers at least a portion of the outer surface of the open lattice tubular sidewall, and the topcoat is at least partially covering the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall.
3. Applicant thus argues that the sandwiched ring prosthesis of Lee (reproduced below) does not include a topcoat at least partially covering the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall.

FIG. 4



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4. Examiner disagrees. As mentioned in the previous rejection, the language "covers" does not necessitate that one layer is directly atop another layer (like a roof still covers the first floor of a multi-story house).
5. Regardless, in order to fully address Applicant's claim amendments it is important to note that the only difference between the claimed device and Lee is the arrangement of the layers.
6. Thus a modification of the prior art to include a stent layer covered with two graft layers would be a rearrangement of the prior art stent graft components. (See MPEP 2411.04). Lee contemplates such a rearrangement (col. 7 lines 21-28), stating that "conceptually the two layers could instead be just the inner and outer surfaces of the same membrane" and that "scaffold members 30 could be secured to either the exterior or the interior surface of the membrane." This specific teaching clearly suggests that a rearrangement of parts is not only possible, but also can be performed using known methods and yielding predictable results.
7. Supporting evidence for this rationale is provided by figure 8 of Lee, teaching the suitability of scaffold members 30 as the inner or outer surface layer (see col. 7 lines 43-50).
8. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Lee such that the stent forms the base layer and the graft layers are directly atop the stent, for the purpose of: providing a two-layered graft with an inside surface of scaffold

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members in order to hold the membrane out against the vascular diameter and not let it contract in diameter (col. 7 lines 43-46).

9. With respect to new claims 171-178, the additional limitation of the prosthesis being "prefabricated" does not distinguish over Lee, because Lee is prefabricated (manufactured, see col. 5 lines 27-29). Regardless, the limitation is a product-by-process limitation that carries no patentable weight in the absence of distinguishing structure. The limitation "wherein the undercoat is in direct contact with the outer surface of the open lattice tubular sidewall" is addressed above, in that Examiner believes it to be an obvious rearrangement of the components of Lee, taught by Lee, for the purpose of holding the membrane out against the vascular diameter and preventing the membrane from contracting in diameter.

Drawings

10. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "open lattice tubular sidewall" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate

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figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 111,124, 125, 139-141,154-155, 169-172 are rejected under 35 U.S.C. 103(a) as being obvious over Lee (U.S. Pat. No.: 5,123,917).

13. Lee discloses a metallic stent 30 with an open lattice tubular sidewall (see fig. 1) wherein at least part of the metallic stent is covered with a coating (graft A, fig. 1) for release of a biologically active material, the coating comprising an undercoat 10 comprising hydrophobic elastomeric material (polyurethane) incorporating an amount of biologically active material (for example heparin, col. 4 lines 58-61).

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14. The coating further comprises a topcoat 20 comprising a biostable non-thrombogenic polymeric material which is different from the hydrophobic elastomeric material (PTFE, Dacron, col. 5 lines 3-7) wherein the topcoat is free of an elutable material (col. 5 lines 7-10, noting that drug impregnation is an option, not a necessity). The topcoat is a barrier which the Examiner is considering to be a control of the release profile of the biologically active material (col. 3 lines 54-67).

15. However, Lee fails to specifically disclose a topcoat at least partially covering the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. It is important to note that this distinction is merely a rearrangement of the disclosed components of Lee.

16. Thus a modification of the prior art to include a stent layer covered with two graft layers would be a rearrangement of the prior art stent graft components. (See MPEP 2411.04). Lee contemplates such a rearrangement (col. 7 lines 21-28), stating that "conceptually the two layers could instead be just the inner and outer surfaces of the same membrane" and that "scaffold members 30 could be secured to either the exterior or the interior surface of the membrane." This specific teaching clearly suggests that a rearrangement of parts is not only possible, but also can be performed using known methods and yielding predictable results.

17. Supporting evidence for this rationale is provided by figure 8 of Lee, teaching the suitability of scaffold members 30 as the inner or outer surface layer (see col. 7 lines 43-50).

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18. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Lee such that the stent forms the base layer and the graft layers are directly atop the stent, for the purpose of: providing a two-layered graft with an inside surface of scaffold members in order to hold the membrane out against the vascular diameter and not let it contract in diameter (col. 7 lines 43-46).

19. With respect to new claims 171-172, the additional limitation of the prosthesis being "prefabricated" does not distinguish over Lee, because Lee is prefabricated (manufactured, see col. 5 lines 27-29). Regardless, the limitation is a product-by-process limitation that carries no patentable weight in the absence of distinguishing structure. The limitation "wherein the undercoat is in direct contact with the outer surface of the open lattice tubular sidewall" is addressed above, in that Examiner believes it to be an obvious rearrangement of the components of Lee, taught by Lee, for the purpose of holding the membrane out against the vascular diameter and preventing the membrane from contracting in diameter.

20. Claims 112, 113, 129, 130, 142, 143, 159, 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Pat. No.: 5,123,917) in view of Berg et al. (U.S. Pat. No.: 5,464,650).

21. Lee is explained supra. However, Lee does not disclose the undercoat comprising an ethylene vinyl acetate copolymer material. Berg teaches the use of ethylene vinyl acetate copolymers as a suitable substrate for drug eluting stents

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(col. 4 lines 19-39, col. 5 line 1). Therefore it would have been obvious to one of ordinary skill in the art to modify the undercoat of Lee to comprise an ethylene vinyl acetate copolymer as taught by Berg, since it is within the skill of an ordinary worker in the art to select a particular material from a given set of known materials suitable for an intended purpose or use. In the instant case, Berg teaches the suitability of ethylene vinyl acetate copolymers as implant material and as drug-eluting material.

22. Claims **114-116, 118-121, 128, 131-138, 144-146, 148-151, 158, 161-168, 173-178** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Pat. No.: 5,123,917) in view of Berg et al. (U.S. Pat. No.: 5,464,650) as applied above, further in view of Mitchell et al. (5,288,711).

23. Lee in view of Berg teaches a coated vascular stent as above; However Lee and Berg appear to lack the coating comprising an antibiotic. Mitchell et al. teaches a stent comprising an antibiotic (Rapamycin) to inhibit proliferation of vascular smooth muscle cells (col. 3, lines 7-31). It would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic, as taught by Mitchell et al., to a coated vascular stent as per Lee and Berg, in order to inhibit proliferation of vascular smooth muscle cells.

24. With respect to new claims 173-178, the additional limitation of the prosthesis being "prefabricated" does not distinguish over Lee, because Lee is prefabricated (manufactured, see col. 5 lines 27-29). Regardless, the limitation is a product-by-process limitation that carries no patentable weight in the absence

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of distinguishing structure. The limitation "wherein the undercoat is in direct contact with the outer surface of the open lattice tubular sidewall" is addressed above, in that Examiner believes it to be an obvious rearrangement of the components of Lee, taught by Lee, for the purpose of holding the membrane out against the vascular diameter and preventing the membrane from contracting in diameter.

25. Claims 117, 122,123, 126, 127, 147, 152, 153, 156, 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Pat. No.: 5,123,917) in view of Mitchell et al. (5,288,711).

26. Lee teaches a coated vascular stent as above however Lee lacks the coating comprising an antibiotic. Mitchell et al. teaches a stent comprising an antibiotic (Rapamycin) to inhibit proliferation of vascular smooth muscle cells (col. 3, lines 7-31). It would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic, as taught by Mitchell et al., to a coated vascular stent as per Lee, in order to inhibit proliferation of vascular smooth muscle cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000

/S. G./

Examiner, Art Unit 3774



DAVID ISABELLA
SPE AU 3774